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No. 06-1498

FILED
NOV 28 2007
OFFICE OF THE CLERK
SUPREME COURT, U.S.

IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC AND PFIZER INC.,

Petitioners,

v.

KIMBERLY KENT, *ET AL.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

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BRIEF OF THE GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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November 28, 2007

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

QUESTION PRESENTED

Whether the Second Circuit defied this Court's holding in *Buckman Co. v. Plaintiffs' Legal Committee* that "[s]tate-law fraud-on-the-FDA claims inevitably conflict" with federal law, 531 U.S. 341, 350 (2001), by holding that state-law claims which depend on proof of fraud on the FDA do *not* conflict with federal law.

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STATEMENT OF INTEREST[1]

The Generic Pharmaceutical Association ("GPhA") is a non-profit, voluntary association comprised of more than 140 manufacturers and distributors in the generic pharmaceutical industry, which accounts for more than 63 percent of prescriptions dispensed in the United States each year. GPhA's members provide American consumers with safe and cost-effective medicines that are bioequivalent to, and have the same therapeutic value as, their brand-name counterparts. These products significantly improve the public's health and welfare while cutting annual healthcare costs by billions of dollars.

GPhA's members—and the millions of Americans who depend on safe, affordable generic medicines—have a strong interest in ensuring that the U.S. Food and Drug Administration ("FDA") is positioned to evaluate all new pharmaceutical products efficiently and, where appropriate, promptly approve those products for commercial marketing. Despite the existence of an expedited pathway for new generic drug products, *see* 21 U.S.C. §§ 355 *et seq.* (the "Hatch-Waxman Act"), FDA's review process remains time-consuming and expensive, and the Agency

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[1] Letters of consent from both parties have been filed with the Clerk of the Court. Pursuant to this Court's Rule 37.6, *amicus* states that no counsel for a party authored any part of this brief and that neither such counsel, nor any party, nor any person or entity other than *amicus*, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

currently faces an unprecedented backlog of pending generic drug applications. *See, e.g.*, Steven Reinberg, *FDA Struggles to Keep Pace With Requests for Generics*, HEALTH DAY, Oct. 4, 2007 ("Despite improved handling of generic drug applications ... FDA has a backlog of more than 1,300 [generic] drugs awaiting approval.").

The Second Circuit's decision threatens to exacerbate that backlog and increase healthcare costs by authorizing state-law claims that pharmaceutical manufacturers defrauded FDA—even if FDA itself has made no such determination. If the appellate court's decision stands, generic and brand-name applicants alike will seek to stave off future claims of fraud the only way they can: by flooding FDA with superfluous documentation that, as this Court recognized in *Buckman Co. v. Plaintiffs' Legal Committee*, "the [Agency] neither wants nor needs." 531 U.S. 341, 351 (2001). That "deluge," *id.*, inevitably will cause further delays in FDA's already-burdened approval process, stifle competition, reduce the flow of safe, effective, and affordable pharmaceutical products to the market, and increase costs for both GPhA's members and the millions of Americans who depend on their products.

At bottom, the Second Circuit's decision in this case blasts a gaping hole in *Buckman*'s holding that federal law precludes such interference with FDA's statutory prerogatives and with the comprehensive statutory framework Congress designed to speed the approval of new drugs. GPhA's 140 members have an obvious interest in seeing this Court restore the integrity of that regime, and respectfully ask this Court to reverse the appellate court's judgment.

SUMMARY OF THE ARGUMENT

Seven years ago, this Court held without dissent that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law," because such "claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives," and "dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the [Food Drug and Cosmetic Act ("FDCA")]." *Buckman*, 531 U.S. at 348, 350.

That ought to be the beginning and end of this case. Plaintiffs here are asserting they were injured by Rezulin®, an FDA-approved drug that defendants lawfully marketed in the United States until they voluntarily withdrew it in March 2000. In order for plaintiffs to maintain their state-law claims—which include fraud, negligence, and misrepresentation, *see* Pet. App. 336a-37a, 343a-45a, 353a-54a—Michigan law expressly requires them not only to prove every element of each asserted claim, *but also* that defendants defrauded FDA by withholding or misrepresenting information they were required to submit to the Agency under specifically enumerated provisions of the FDCA, *and* that FDA would not have approved or maintained its approval of Rezulin® if defendants had complied with those specifically enumerated provisions of the FDCA. *See* MICH. COMP. LAWS § 600.2946(5)(a) (2007) (citing 21 U.S.C. §§ 301-21, 331-43-2, 344-46a, 347-53, 355-60, 360b-76, 378-95).

Buckman squarely held that federal law preempts state-law claims predicated on allegations that a

manufacturer defrauded FDA; Michigan law specifically requires plaintiffs to prove that defendants defrauded FDA in order to prevail; under *Buckman*, plaintiffs' claims are preempted.

The Second Circuit, however, attempted to distinguish *Buckman* on the ground that in that case, "proof of fraud against the FDA [wa]s *alone sufficient* to impose liability," Pet. App. 20a (emphasis in original), while in this case, proof of fraud against FDA merely would permit "pre-existing common law claims [to] survive." Pet. App. 21a. That assertion is both factually inaccurate and legally irrelevant.

It is factually inaccurate, because the alleged fraud on the FDA in *Buckman* merely served as the predicate false representation in a common-law fraudulent misrepresentation action, and that cause of action in turn required (among other things) proof of injury and proximate cause. *See In re Orthopedic Bone Screw Liab. Litig.*, 159 F.3d 817, 822 (3d Cir. 1998), *rev'd sub nom. Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (explaining that plaintiffs' claim of fraud on the FDA "track[s] the elements of a common law cause of action for fraudulent misrepresentation"). The Second Circuit thus flatly erred in asserting that "proof of fraud against the FDA [wa]s *alone sufficient* to impose liability" in *Buckman*. Pet. App. 20a (emphasis in original). It was not.

Indeed, if anything, the Michigan statute at issue in this case conflicts even more directly with federal law than the common-law claims at issue in *Buckman*. After all, the Michigan statute at issue here *expressly conditions* plaintiffs' common-law

claims on proof that defendants defrauded FDA in the course of making certain FDCA-mandated disclosures, while the common-law fraud claims in *Buckman merely happened* to be premised on allegations that the defendants in that case defrauded FDA in the course of making certain FDCA-mandated disclosures.

But even if the appellate court were right about the nature of the claims in *Buckman*, its putative distinction of those claims is legally "immaterial"—as the Sixth Circuit held when it addressed this very issue. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004). Whether proof of fraud on the FDA is "*alone sufficient* to impose liability," Pet. App. 20a (emphasis in original), or instead serves as a statutory prerequisite to the maintenance of "pre-existing common law claims," *id.* 21a, claims that *depend* on proof of fraud on the FDA necessarily impinge upon FDA's comprehensive authority to "detect[], deter[], and punish[] false statements made during [the] approval process[]," *Buckman*, 531 U.S. at 349, and impose unwarranted burdens on the Agency, the industry it regulates, and ultimately, the consuming public. *Id.* at 350-51.

Contrary to the Second Circuit's assertions, those concerns apply with no less force here than in *Buckman*, and allowing these claims to proceed would have a particularly severe impact on the generic pharmaceutical industry—which depends on an expedited review and approval process that Congress established to speed the entry of generic drugs into the market. *See* 21 U.S.C. §§ 355 *et seq.* Continued pursuit of the claims at issue here thus would conflict with federal law no less than the

common-law claims this Court held to be preempted in *Buckman*. Accordingly, this Court should reverse the judgment.

ARGUMENT

The Second Circuit Defied This Court's Holding In *Buckman* That "State-Law Fraud-On-The-FDA Claims Inevitably Conflict" With Federal Law, By Holding That State-Law Claims Which Depend On Proof Of Fraud On The FDA Do *Not* Conflict With Federal Law.

The Second Circuit erred by holding that state-law claims which depend on proof of fraud on the FDA do not conflict with federal law and thus are not preempted. Indeed, that holding defies this Court's decision in *Buckman*, which expressly declared that "state-law fraud-on-the-FDA claims inevitably conflict with" federal law and "are therefore impliedly pre-empted." 531 U.S. at 348, 350. That decision controls here and requires dismissal of plaintiffs' claims. Plaintiffs are free to assert their claims that defendants defrauded FDA by lodging a complaint with the Agency, but *Buckman* unambiguously precludes them from litigating such claims in court.

The Second Circuit, however, asserted that *Buckman* does not control this case because the Michigan statute at issue here (in alleged contrast to the plaintiffs' claims in *Buckman*) does "not invent new causes of action premised on fraud against the FDA," Pet. App. 18a, but instead authorizes plaintiffs to "assert[] claims that sound in traditional state tort law," *id.* at 19a. *See also id.* at 20a ("[A]ll of the claims ... in this case are premised on traditional duties between a product manufacturer

and Michigan consumers. None of them derives from, or is based on, a newly-concocted duty between a manufacturer and a federal agency.").

But that simply is not so. The *Buckman* plaintiffs did not assert some "new cause[] of action premised on" claims that the defendants in that case violated a "newly-concocted duty" they owed to FDA. Instead, they brought a plain-vanilla fraudulent misrepresentation claim that merely happened to proceed from allegations that the defendants' intentionally false representations to FDA resulted in their injuries. *See In re Orthopedic Bone Screw Liab. Litig.*, 159 F.3d at 821-22 (detailing plaintiffs' allegations of fraud and explaining that their claim "track[s] the elements of a common law cause of action for fraudulent misrepresentation: (1) a representation of fact, opinion, intention or law; (2) knowledge of its falsity; (3) an intent to induce reliance; (4) justifiable reliance; and (5) resulting injury") (citing RESTATEMENT (SECOND) OF TORTS §§ 525 *et seq.*).

That, of course, is why the Third Circuit's decision in *Buckman* went on to consider whether the plaintiffs' "complaints ... state[d] a claim for fraudulent misrepresentation," *see id.* at 826-29, and eventually concluded that "what we know about tort law generally makes us unwilling to say that all of the plaintiffs' claims will fail." *Id.* at 826 (quoting RESTATEMENT (SECOND) OF TORTS § 310 for the proposition that in certain circumstances, "[a]n actor who makes a misrepresentation is subject to liability to another for physical harm which results from an act done by ... third person in reliance upon the truth of the representation")).

If anything, then, it is the Michigan statute at issue in this case—and not the plaintiffs' common-law claims of fraudulent misrepresentation in *Buckman*—that depends on "a newly-concocted duty between a manufacturer and a federal agency." Pet. App. at 20a. After all, the Michigan statute permits traditional state-law claims to proceed *only* if the defendant-manufacturer withheld or misrepresented information it was required to submit to FDA under the "federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395." MICH. COMP. LAWS § 600.2946(5)(a).

The Michigan statute's express reference to the FDCA's disclosure provisions refutes the appellate court's suggestion that the duties at issue here somehow predate the federal regulatory scheme. *Cf.* Pet. App. at 18a, 19a-20a. A statute that expressly conditions liability on proof that a defendant committed fraud in connection with specific federally mandated disclosures obviously postdates the federal scheme and renders "the existence of these federal enactments ... a critical element in [plaintiffs'] case." *Buckman*, 531 U.S. at 353. Regardless of whether plaintiffs' claims sound in fraud, negligence, products liability, or something else entirely, the Michigan statute at issue here unambiguously requires plaintiffs not only to prove each element of every asserted claim, *but also* that defendants defrauded FDA in the course of making certain specific FDCA-mandated disclosures regarding Rezulin®, *and* that FDA would not have approved or maintained its approval of Rezulin® had it not been defrauded. MICH. COMP. LAWS § 600.2946(5)(a).

The Second Circuit nonetheless sought to evade that conclusion by asserting that the Michigan statute merely creates an optional affirmative defense without formally altering the elements of a traditional common-law cause of action. Pet. App. 24a ("[T]he Michigan law in question does no more than create a defense that drug makers may invoke, *if they so decide*, and ... it is not up to the plaintiff to prove fraud as an element of his or her claim.") (emphasis added) (citing *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 134 (Mich. 2003)); *see also id.* at 23a ("The existence of properly-obtained FDA approval becomes germane *only if a defendant company chooses to assert an affirmative defense.*") (emphasis added).

With all due respect to the appellate court, that putative distinction both misses the point and turns a blind eye to the reality of pharmaceutical products-liability litigation. It misses the point, because as soon as the manufacturer of an FDA-approved product meets its razor-thin burden of showing that its product was FDA-approved (as plaintiffs necessarily concede Rezulin® was here), the burden unquestionably shifts to the plaintiff to prove that one of the statutory exceptions to § 600.2946(5) applies. *See, e.g., Zammit v. Shire US, Inc.*, 415 F. Supp. 2d 760, 767 (E.D. Mich. 2006). That, of course, helps explain why plaintiffs in this case affirmatively pleaded in their original complaints that defendants had defrauded FDA—that is, that the essential prerequisite to suit set forth in § 600.2946(5)(a) was satisfied in this case. *See, e.g.*, Pet App. 337a (¶¶ 22(F), 22(H), 23); *id.* 344a-45a (¶ 8); *id.* 353a-54a (¶¶ 7(F), 7(H), 8).

And it turns a blind eye to the reality of pharmaceutical products-liability litigation, because pharmaceutical defendants—no less than other sophisticated litigants—are not in the business of leaving dispositive statutory defenses on the cutting-room floor. That, too, helps explain why plaintiffs did not bother waiting for defendants to invoke § 600.2946(5), but affirmatively pleaded in their original complaints that the terms of § 600.2946(5)(a) were satisfied in this case. *See id.*

In sum, the claims at issue in this case are materially indistinguishable from the ones this Court held to be preempted in *Buckman*. As in *Buckman*, liability in this case depends on proof that defendants defrauded FDA in the course of making certain FDCA-mandated disclosures. And as in *Buckman*, permitting these claims to proceed would require a court (or jury) to place itself in FDA's shoes, determine whether FDA was defrauded, and if so, speculate as to whether FDA would have approved or maintained its approval of Rezulin® in the absence of such fraud. That is precisely the kind of inquiry that *Buckman* held would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives" and thereby "exert an extraneous pull on the scheme established by Congress." 531 U.S. at 350, 353.

But even if the appellate court had identified a legally relevant distinction between the claims at issue in *Buckman* and the claims at issue here (which it did not), it provided no sound basis for concluding that the adverse practical consequences of permitting these claims to proceed would be less

significant here than in *Buckman*. After all, if states may condition the maintenance of products-liability and other common-law claims on proof that a manufacturer defrauded FDA in the course of fulfilling its FDCA-mandated disclosure duties, then manufacturers will take the only preventative course of action available to them: they will "submit a deluge of information [to FDA] that the Administration neither wants nor needs," *Buckman*, 531 U.S. at 351, and that "deluge" inevitably will disrupt FDA's ability to evaluate pending applications efficiently. *Id.*

The resulting burdens would take a particularly severe toll on generic drug applicants—and on the expedited approval process Congress established to speed the entry of generic drugs to the market. Indeed, more than two decades ago, Congress recognized the value of generic drug products by establishing a streamlined process designed to expedite FDA's review and approval of new generic drug applications and encourage manufacturers to develop safe, effective, and affordable generic medicines. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in scattered sections of titles 21, 35, and 42 U.S.C., and known as the "Hatch-Waxman Act" or "Hatch-Waxman"); *see also Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004) (explaining that Hatch-Waxman was "[e]nacted to expedite the process by which companies gain approval to sell generic versions of already-approved brand-name drugs"); *Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988) ("The purpose of [Hatch-Waxman] was to increase competition in the drug

industry by facilitating the approval of generic ... drugs.").

Congress has made a number of modifications to Hatch-Waxman over the years, *see, e.g.*, Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), Pub. L. No. 108-173, 117 Stat. 2066 (2003), but its essential feature remains the same: while new drug applicants generally must submit volumes of clinical data and other information to show that a proposed new drug is safe and effective, "applicants who wish to manufacture generic versions [of a previously approved drug product] may instead complete an Abbreviated New Drug Application, or ANDA, which relies on the FDA's previous determination that the drug is safe and effective." *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998); *see also* 21 U.S.C. § 355(j). Indeed, so long as the generic applicant demonstrates that its proposed generic drug product is bio- and therapeutically equivalent to a previously approved drug, its product may be approved by FDA without undergoing the "many years" of clinical trials branded manufacturers must conduct and without the "thousands of pages" of data branded manufacturers must submit to the Agency. *See* Br. of Petitioners at 5 & n.1.

Suffice it to say, Abbreviated New Drug Applications for generic pharmaceuticals are just that—*abbreviated*—and the expedited review process they make possible has been remarkably successful. As a direct result of Hatch-Waxman's streamlined application and approval process, generic medicines now account for more than 60 percent of all prescriptions dispensed in the United States (up

from 18.6 percent in 1984), but less than 20 percent of every dollar spent on prescription drugs. *See, e.g.*, Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993-94 (2007); *see also* Laura J. Robinson, *Analysis of Recent Proposals To Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47, 48 (2003) ("In effect, the Hatch-Waxman amendments created the modern generic drug industry.").

The Michigan statute at issue in this case nonetheless threatens to compromise Hatch-Waxman's expedited generic approval process by specifically authorizing plaintiffs to second-guess the sufficiency of disclosures made in connection with an abbreviated new drug application. *See* MICH. COMP. LAWS § 600.2946(5)(a) (identifying disclosures made pursuant to Hatch-Waxman as grounds for potential liability). If this Court authorizes such claims to proceed, the volume of information submitted with generic drug applications will increase dramatically as manufacturers seek to stave off future claims of liability, and the Agency's already-unmanageable backlog of more than 1,300 pending generic drug applications will swell even further as regulators begin to wade through those newly voluminous applications.

The net effect will be increased delays in the approval of generic drugs as FDA struggles to process expanded generic drug applications—reducing market competition between branded and generic products, increasing pharmaceutical costs, and ultimately depriving American consumers of prompt access to safe, effective, and affordable generic medicines. Permitting claims like the ones

at issue in this case to proceed thus would be demonstrably at odds with Congress's unambiguously expressed intent "'to make available more low cost generic drugs,'" *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1316 (D.C. Cir. 1998) (quoting H.R. Rep. No. 98-857 at 14 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2647), and this Court thus should reject the appellate court's efforts to evade *Buckman*.

CONCLUSION

For the foregoing reasons, this Court should reverse the judgment of the Second Circuit.

Respectfully submitted,

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November 28, 2007